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10/828,630	04/09/2004	Jill E. Parker	AFD 503	5340

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NAVARRO, ALBERT MARK	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/828,630
Filing Date: April 09, 2004
Appellant(s): PARKER ET AL.

Heydon
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 3, 2006 appealing from the Office action mailed October 6, 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

Claims 1 and 3-4 are rejected.

Claim 2 is objected to as being a substantial duplicate of claim 1. Both claims are directed to the identical strain of Bacillus anthracis having deposit accession number ATCC PTA-3162.

Claims 5-10 have been withdrawn from consideration as being drawn to a non-elected invention.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows: Claim 2 is objected to for being a substantial duplicate of claim 1, in that both claims are directed to the exact same strain, ATCC PTA-3162.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,387,665	Ivins et al	5-2002
US 2002/0055628	Keim et al	May 2002
US 2003/0143636	Simonson	7/2003

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

A). The rejection of claim 1 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic strains, does not reasonably provide enablement for vaccine strains.

Facts that should be considered in determining whether a specification is enabling, or if it would require an undue amount of experimentation to practice the invention include: (1) the quantity of experimentation necessary to practice the invention, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior

art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. See In re Wands, 858 F.2d 731,737, 8 USPQ2d 1400, 1403 (Fed. Cir. 1988). The Federal Circuit has noted, however, that only those factors that are relevant based on the facts need to be addressed. See Enzo Biochem. Inc. v. Calgene, Inc. 188 F.3d 1362, 1371, 52 USPQ2d 1129, 1135 (Fed. Cir 1999).

First, Simonson, US Publication (2003/0143636) sets forth that in dealing with anthrax vaccination "vaccine efficacy in one animal model cannot be compared to the protection afforded other animal immunized with the same vaccines or challenged with the same anthrax strains. This also clearly points out the inherent difficulty in extrapolating results of anthrax vaccine protection in animals to that in patients." This teaching directly addresses factors 1, 4, 5, 6, 7 and 8.

Second, Applicants specification provides no working examples demonstrating prevention with the strain of the invention. To the contrary, Example 9 of the specification demonstrates a lethality study comparing the Alls/Gifford strain of the invention with the Sterne strain and shows the results in Figure 5. While Applicants note a time to death to be prolonged following infection with the Alls/Gifford strain, Applicants will appreciate that the ultimate percent survival in both cases was zero percent. This directly affects Factors 1, 2, 3, 4 and 8.

A vaccine "must by definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough." In re Wright, 999 F.2d 1557,1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

Given the lack of guidance, lack of working examples, and the unpredictable

nature of the invention, one of skill in the art would be forced into excessive experimentation in order to practice the instantly claimed invention.

B). Claims 3-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Ivins et al.

The claims are directed to a mutated strain of Bacillus anthracis having: presence of pX01 plasmid, synthesis of Diazoluminomelanin, sensitivity to Penicillin, ability to be lysed by Cherry gamma phage, non-hemolytic, production of nitrite from nitrate, and thermal resistance up to about 240 degrees Celsius.

Ivins et al (US Patent Number 6,387,665) disclose of spore forming strain B. anthracis ΔSterne-1(pPA102). (See column 8).

It is noted that Applicants specification, page 12, sets forth that Sterne strains, contain the pX01 plasmid, produce diazoluminomelanin, sensitivity to Penicillin, ability to be lysed by Cherry gamma phage, non-hemolytic, and produce nitrite from nitrate. It is further noted that Figure 2 of the instant application shows the thermal resistance of both the Sterne strain and the Alls/Gifford strain of the instant invention. While the CFU of the Sterne strain do show a decrease at about 240 degrees, it does not drop to zero. Given that the claim does not set forth what amount of thermal resistance must be present, the survival of even a single strain at about 240 degrees is deemed to meet the limitation of "thermal resistance up to about 240 degrees."

Furthermore, since there are multiple Sterne strains of Bacillus anthracis and claim 4 does not recite which particular strain is being compared, strain B. anthracis

ΔSterne-1(pPA102) is deemed to be able to delay the onset of death relative to other random Sterne strains, as there will inherently be a small but normally distributed variation from one strain compared to another.

Accordingly, Ivins et al disclose of each and every limitation of the claimed mutated strain.

C). Claims 3-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Keim et al.

The claims are directed to a mutated strain of Bacillus anthracis having: presence of pX01 plasmid, synthesis of Diazoluminomelanin, sensitivity to Penicillin, ability to be lysed by Cherry gamma phage, non-hemolytic, production of nitrite from nitrate, and thermal resistance up to about 240 degrees Celsius.

Keim et al (US Publication 2002/0055628) disclose of vaccine strains, Sterne STI-1 and V770-NP1. (See paragraph 36).

It is noted that Applicants specification, page 12, sets forth that Sterne strains, contain the pX01 plasmid, produce diazoluminomelanin, sensitivity to Penicillin, ability to be lysed by Cherry gamma phage, non-hemolytic, and produce nitrite from nitrate. It is further noted that Figure 2 of the instant application shows the thermal resistance of both the Sterne strain and the Alls/Gifford strain of the instant invention. While the CFU of the Sterne strain do show a decrease at about 240 degrees, it does not drop to zero. Given that the claim does not set forth what amount of thermal resistance must be present, the survival of even a single strain at about 240 degrees is deemed to meet the

limitation of "thermal resistance up to about 240 degrees."

Furthermore, since there are multiple Sterne strains of Bacillus anthracis and claim 4 does not recite which particular strain is being compared, strain Sterne STI-1 and V770-NP1 are deemed to be able to delay the onset of death relative to other Sterne strains.

Accordingly, Keim et al disclose of each and every limitation of the claimed mutated strain.

(10) Response to Argument

Appellants argue:

A). 1) Claim 1 does not describe a perfected, commerically viable embodiment and should be read in light of the specification as a new strain having "unique characteristics that are important in designing a vaccine" and a vaccine strain "from which may be produced an improved anthrax vaccine" and that "will enable identification of new genes that contribute to the pathogenesis of the organism and thereby elucidate new antigens that play a role in eliciting a specific, protective immune response early in the infection process." (Specification pages 8 & 9).

2) That the Simonson reference does not contain the phrase "vaccine strain" and is instead focused on a commercially viable product.

B). Appellants assert that the cited references do not teach of the limitation of "thermal resistance."

C). Appellants assert that the cited references do not teach of the limitation of "delayed onset of death in a laboratory animal."

RESPONSE:

A). Appellants argue that claim 1 should be read in light of the specification which sets forth that a "vaccine strain of Bacillus anthracis ***from which may be produced*** an improved anthrax vaccine." (Emphasis added). However, it is precisely the claim language of "vaccine" which requires a reasonable degree of protection to be deemed enabled. A vaccine "must be definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough." In re Wright, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). Furthermore, Example 9 of the specification demonstrates a lethality study comparing the Alls/Gifford strain of the invention with a Sterne strain and shows the results in Figure 5. While Appellants note a time to death to be prolonged following infection with the Alls/Gifford strain, Appellants will appreciate that the ultimate percent survival in both cases was zero percent. Simply stated, a zero percent survival is not commensurate in scope with claim language reciting a "vaccine."

Appellants further assert that Simonson does not contain the phrase "vaccine strain" and is instead focused on a commercially viable product. However, Simonson sets forth that "***vaccine efficacy*** in one animal model ***cannot be compared*** to the protection afforded other animals ***immunized with the same vaccines or challenged***

with the same anthrax strains. This also clearly points out the ***inherent difficulty*** in extrapolating results of anthrax vaccine protection in animals to that in patients." (See paragraph number 50) (Emphasis added). Furthermore, these difficulties are in addition to Appellants Example 9, in which ***zero percent*** of "vaccine" recipients were protected.

B). Appellants assert that the cited references do not teach of the limitation of "thermal resistance." However, Figure 2 of the instant application shows the thermal resistance of both a Sterne strain and the Alls/Gifford strain of the instant invention. While the CFU of the Sterne strain do show a decrease at about 240 degrees, it does not drop to zero. Given that the claim does not set forth what amount of thermal resistance must be displayed, the survival of even a single CFU strain at about 240 degrees is deemed to meet the limitation of "thermal resistance up to about 240 degrees." Since the Patent office does not have the facilities for examining and comparing Applicants product with the product of the prior art reference, the burden is on Applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed product and the product of the prior art. *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

C). Appellants assert that the cited references do not teach of the limitation of "delayed onset of death in a laboratory animal." However, since there are multiple distinct mutant Sterne strains of Bacillus anthracis (e.g., Sterne STI-1 and V770-NP1), and that claim 4

does not identify any one particular strain to be compared with, Sterne STI-1 and V770-NP1 are deemed to be able to delay the onset of death relative to other Sterne strains, since each strain will have an inherent but small variation in survival time when compared to each other. Since the Patent office does not have the facilities for examining and comparing Applicants product with the product of the prior art reference, the burden is on Applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed product and the product of the prior art. *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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July 5, 2006

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